

### REMARKS

The specification has been amended to insert a cross-reference to the PCT application and foreign priority document. Claims 4 and 6 have been rewritten as claims 25 and 26, respectively, to clarify the fragments to which the antibodies or antibody fragments bind (25 and 26) and to add a step for detecting bound antibody (26). Claims 5 and 8 have been amended to refer to the new claims and to simplify the language. Claims 9-11 have been canceled. It is believed that none of these amendments constitute new matter, and their entry is therefore requested.

Applicants note the Draftsperson's objection to the drawings. Since the objections related to informalities, it is believed that a proposed drawing correction is not required. The objections will be obviated when formal drawings are filed, once allowable subject matter has been found.

Claim 4 was rejected under 35 USC §101 for being directed to non-statutory subject matter. The Examiner contends that the claim encompasses naturally occurring as well as synthetic compositions. It is submitted that the Examiner is incorrect in her contention. Claim 25 is directed to a monoclonal antibody or a recombinant antibody fragment. Since neither of these products occur in nature, i.e., they are made by the intervention of man, it is submitted that the rejection is improper. Withdrawal of this rejection is requested.

Claims 4-6 and 8-11 were rejected under 35 USC §112, second paragraph, for being indefinite. It is believed that the cancellation of claims 9-11 obviates that portion of the rejection. With respect to the portion of the rejection directed to claims 4 and 6, it is believed that newly presented claims 25 and 26 clearly identify the fragments to which the monoclonal antibodies or the recombinant antibody fragments bind, and that this amendment obviates this portion of the rejection. With respect to the portion of the rejection directed to claims 6-11, it is believed that newly presented claim 26 specifies the necessary steps for the immunoassay, and that this amendment obviates this portion of the rejection. Withdrawal of this rejection is requested.

Claims 4-6 and 8-11 were rejected under 35 USC §112, first paragraph, for lack of written description. In essence, the Examiner contends that the specification does not demonstrate that Applicants were in possession of every monoclonal antibody which would bind to the specified osteocalcin fragment. It is submitted that the Examiner is in error in this rejection.

Applicants submit that the issue of adequate written description is dependent on the facts of each individual case and the mere citation of case law for certain broad propositions cannot be taken out of the context of the facts of the specific cases. The presently claimed invention is directed to a monoclonal antibody or a recombinant antibody fragment which binds to a specific epitope. The epitope is selected from the group consisting of:

i) a fragment which spans from amino acid in position 7 to amino acid in position 30 of the amino acid sequence set forth in SEQ ID NO:2 in which all three glutamic acids in positions 17, 21 and 24 of said sequence are gamma-carboxylated, and


ii) a fragment which spans from amino acid in position 6 to amino acid in position 30 of the amino acid sequence of SEQ ID NO:2, and that all three glutamic acids in the positions 17, 21 and 24 of said sequence are gamma-carboxylated.

The case law holds that the specification must set forth sufficient structure and/or physical properties to demonstrate that Applicants were in possession of the invention. It is submitted that monoclonal antibodies and recombinant antibody fragments all have known structure and have known physical properties. Thus, the designation of the invention as a monoclonal antibody or a recombinant antibody fragment in the specification demonstrates to a skilled artisan that Applicants were in the possession of the invention. Furthermore, the disclosure that the monoclonal antibodies or recombinant antibody fragments bind to a specified epitope provides a further description of the properties of the antibodies or antibody fragments. Thus, it is submitted that the specification contains sufficient structure and/or physical properties to demonstrate that Applicants were in possession of the invention. Furthermore, five separate species of the genus are disclosed, which Applicants submit is sufficient under the case law. It is submitted that the disclosure of five separate species clearly and reasonably demonstrates to a skilled artisan that Applicants were in possession of the claimed invention. Thus, Applicants submit that the disclosure in the specification and the facts of the present application, demonstrate that the specification contains an adequate written description of the invention. Accordingly, withdrawal of this rejection is requested.

Claims 4-6 and 8-11 were rejected under 35 USC §112, first paragraph, for lack of enablement. The claims directed to specific monoclonal antibodies have been canceled. The remaining claims are directed to the generic invention. Applicants submit that the production of

monoclonal antibodies and screening the monoclonal antibodies for specificity is routine and readily accomplished by skilled artisans. Thus, no undue experimentation is required to practice the claimed invention. If the Examiner believes that the specification is not enabling, she is requested to present the necessary analysis as required by *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971) and *In re Wands*, 8 USPQ2d 1400 (Fed Cir 1988). Thus, it is submitted that the present claims are fully enabled by the specification. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the cited prior art. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

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Attachment: Marked-Up Copies of Amendments



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Mark-ups, Page 1

**MARKED-UP COPY OF THE AMENDED CLAIMS**

5 (amended). A cell line producing the monoclonal antibody [according to] of claim [4] 25.

8 (twice amended). The immunoassay [according to] of claim [6] 26, [characterized in that] wherein the non-competitive immunoassay is carried out in either a one-step or a two-step incubation procedure.